



Drug Development Committee

February 26, 2004

Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Suite 325
Rockville, MD 20852

RE: ESSENTIAL INVENTIONS, INC. PETITION TO USE BAYH-DOLE AUTHORITY TO PROMOTE ACCESS TO RITONAVIR, SUPPORTED BY NIAID CONTRACT NIAID CONTRACT NO.: AI27220

Dear Dr. Rohrbaugh:

The AIDS Treatment Activist Coalition (ATAC) is a national coalition of AIDS activists, many living with HIV/AIDS, working together to end the AIDS epidemic. ATAC's Drug Development Committee (DDC) works with government, academia and Industry to provide a community perspective to the development of new HIV drugs and the utilization of HIV therapies. We are writing to support the petition by Essential Inventions, Inc., requesting that you exercise the "march-in" provisions of the Bayh-Dole Act with respect to Norvir, a government funded invention by Abbott Laboratories.

Abbott shocked the AIDS affected community and endangered many lives by increasing the price of Norvir by 400% in December 2003. A full treatment of Norvir will now cost over \$46,000, making it by far the most expensive protease inhibitor on the market.

The most common use of Norvir is as a "booster" for other protease inhibitors. For six of the seven non-Abbott protease inhibitors on the market, boosting with Norvir is necessary to achieve maximum medical benefits. Thus, Abbott's price increase has anticompetitively raised the price of its competitors' products.

Abbott did not raise the price of its own Norvir-boosted protease inhibitor, Kaletra. The disparity in the price of Kaletra versus other Norvir boosted protease combinations will negatively impact the health and safety of people with HIV/AIDS in a number of ways. Some insurers may limit people's access to protease inhibitor combinations other than Kaletra and may ban reimbursement for Norvir in its full dose. Many could be left with substandard treatment options, leading to increased risk for illness and even loss of life.

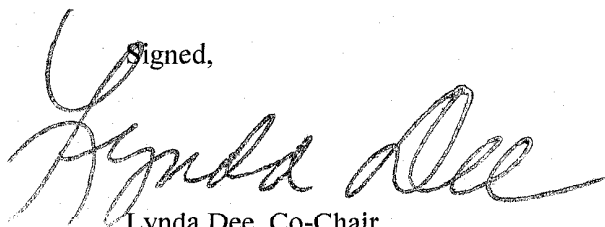
AIDS Drug Assistance Programs, which are already capping enrollment and rationing access to medications because of a lack of needed resources, will see their ranks swell as people are forced out of private sector insurance options and will feel financial strain by commitments to pay private insurance medicine co-payments for many patients. Pharmaceutical assistance programs operated by cities under Title I of the Ryan White Act and non-profit treatment clinics around the country are being saddled with the full price increase to the detriment of their ability to serve their patients.

The price increase will also have a negative impact on the development of new protease inhibitors that require a boosting dose of Norvir. For example, tipranavir, a new protease inhibitor by Boehringer-Ingelheim, needs to be boosted with 400 milligrams of Norvir. At the new Norvir price, the booster component alone for tipranavir will cost over \$16,000 a year, destroying the drug's potential to compete with other protease inhibitors for a share of the market for first-line treatments. Therapies that require Norvir boosting may now be abandoned due to the astronomical price of Norvir. This threatens "salvage" patients, the very people who need new anti-HIV drugs the most because they have become resistant or intolerant to all other marketed anti-viral options.

We endorse Essential Inventions' proposed terms for a Bayh-Dole license. First, the license should be open to all qualified applicants so that competitive forces can work to lower prices to consumers to the lowest possible amount, consistent with providing due reward to the patent holder. Second, under the circumstances, we believe that Essential Inventions' proposed royalty term to Abbott of 5% of net generic sales is generous. Third, we endorse the concept of a research and development contribution based on sales of generic Norvir to ensure that use of Bayh-Dole rights does not detract from needed efforts to fund research and development for new HIV/AIDS treatments. We agree with Essential Inventions' petition that there may be multiple ways to structure the fund, and to ensure that the fund is transparent and directed toward research and development of new AIDS drugs.

We urge that you act with great haste to alleviate the negative impacts to health and welfare that people with AIDS are facing because of Abbott's unreasonable and abusive pricing of a government funded invention.

Signed,



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Gay Men's Health Crisis (GMHC), NYC
Treatment Action Group (TAG), NYC
HealthGap
Center for AIDS, Houston
Test Positive Aware Network, Chicago
The Access Project, NYC
AIDS Treatment Data Network, NYC
The Harm Reduction Coalition, NYC
Being Alive, Long Beach
Program for Wellness Restoration, Houston
AIDS Action Baltimore
Community HIV/AIDS Mobilization Project (CHAMP), NYC
Essential Innovations, Inc.
AIDS Treatment Activists Coalition (ATAC) Save AIDS Drug Assistance Program (ADAP) Committee
Ohio AIDS Coalition

Hyacinth AIDS Coalition, New Brunswick, NJ
Positive for Positives, Cheyenne, Wyoming
Title II Community AIDS National Network (TIICAN)
New Mexico Poz Coalition
Planet Poz, Albuquerque , NM
Wyoming: Positives For Positives
Foundation for Integrative AIDS Research (FIAR), Brooklyn, NY
Being Alive, Los Angeles
Housing Works, Albany Advocacy Center
NYC AIDS Housing Network
Michigan Positive Action Coalition (MI-Poz)
New Mexico AIDS InfoNet
The Peoples Caucus, San Antonio, TX
San Francisco AIDS Foundation
ACT UP/NY
ACT UP East Bay, Oakland, CA
HIV Advocacy Council of Oregon and Southwest Washington
International Foundation for Alternative Research in AIDS (IFARA)
AIDS Action Project Northwest (AAPNW), Portland, OR
Organization of HIV Healthcare Providers
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CC: Mark L. Rohrbaugh, Ph.D., J.D.,
Director, Office of Technology Transfer
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